# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

# FORM 8-K

CURRENT REPORT Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): November 11, 2014

# FATE THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation) **001-36067** (Commission File Number)

65-1311552 (I.R.S. Employer Identification No.)

3535 General Atomics Court, Suite 200 San Diego, CA 92121 (Address of principal executive offices, including zip code)

(858) 875-1800

(Registrant's telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

□ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

□ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

□ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

□ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

#### Item 2.02 Results of Operations and Financial Condition.

On November 11, 2014, Fate Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended September 30, 2014. A copy of the press release is attached as Exhibit 99.1.

The information in this Item 2.02 of this Current Report on Form 8-K, including Exhibit 99.1, is being furnished and shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended ("Exchange Act") or otherwise subject to the liability of that section, nor shall such information be deemed incorporated by reference in any filing under the Exchange Act or the Securities Act of 1933, as amended, regardless of the general incorporation language of such filing, except as shall be expressly set forth by specific reference in such filing.

## Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description	
99.1	Press release dated November 11, 2014	

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## SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

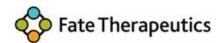
Date: November 12, 2014

# FATE THERAPEUTICS, INC.

By: <u>/s/ J. Scott Wolchko</u> J. Scott Wolchko Chief Financial Officer and Chief Operating Officer

# EXHIBIT INDEX

Exhibit No.	Description	
99.1	Press release dated November 11, 2014	
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#### Fate Therapeutics Reports Third Quarter 2014 Financial Results

#### Phase 1b PROMPT Study in Pediatric Hematologic Malignancies Open for Enrollment

#### Second Data Review in Phase 2 PUMA Study Expected in 4Q14

#### Presenting Effects of Ex Vivo Programming on Mobilized Peripheral Blood at ASH

**San Diego, CA** — **November 11, 2014** — Fate Therapeutics, Inc. (NASDAQ: FATE), a biopharmaceutical company engaged in the discovery and development of adult stem cell modulators to treat orphan diseases, today provided program updates and announced financial results for the third quarter ended September 30, 2014.

"Our Phase 2 PUMA study of PROHEMA® is approaching the second planned data safety review by the independent data monitoring committee. We expect this review to occur during the fourth quarter of 2014, and look forward to providing a clinical update based on data available from the first 20 patients in the study," said Christian Weyer, M.D., M.A.S., President and Chief Executive Officer of Fate Therapeutics. "We are also pleased with the expansion of our PROHEMA clinical investigation into pediatric patients with hematologic malignancies and rare genetic disorders — pediatric patients are actively being screened for enrollment in our PROMPT study, and we expect to open our PROVIDE study in the fourth quarter of 2014."

"Looking toward 2015, we are excited about our emerging pipeline of hematopoietic cellular therapeutics to address severe, life-threatening diseases. At the upcoming American Society of Hematology annual meeting, we will present new research on the effects of *ex vivo* programming on mobilized peripheral blood. We have systematically studied the effects of *ex vivo* programming on this commonly used allogeneic cell source, evaluating different small molecule modulators and profiling their effects on both hematopoietic stem cells and T cells. Additionally, building upon our proprietary reprogramming platform, we have strengthened our commitment to researching therapeutic applications of human induced pluripotent stem cell-derived myogenic and hematopoietic cells."

#### **Recent Program Developments & Upcoming Milestones**

• Second Data Review of Phase 2 PUMA Study of PROHEMA Expected in 4Q14. During the fourth quarter of 2014, the Company expects the independent Data Monitoring Committee (iDMC) to conduct a second data safety review of the Company's PUMA study, a randomized, controlled, open-label Phase 2 clinical trial of PROHEMA in adult patients undergoing double umbilical cord blood transplantation for the treatment of hematologic malignancies. Following the completion of this second review by the iDMC, which is expected to include clinical data from approximately 12 PROHEMA patients and 8 control patients, the Company intends to provide an update on the PUMA study. In its first data review, conducted in August 2014, the iDMC did not identify any safety signals and supported continuation of the study. Full data on the primary efficacy endpoint from the 60-patient, Phase 2 clinical trial are anticipated to be available in mid-2015.

- Phase 1b PROMPT Study in Pediatric Hematologic Malignancies Open for Enrollment. In October 2014, the Company commenced the Phase 1b PROMPT study of PROHEMA in pediatric patients undergoing single umbilical cord blood transplantation for the treatment of hematologic malignancies. The clinical trial is designed to enroll up to 18 patients, between the ages of 1 and 18, at three leading U.S. pediatric transplant centers. During the fourth quarter of 2014, the Company also expects to initiate the Phase 1b PROVIDE study of PROHEMA in pediatric patients undergoing single umbilical cord blood transplantation for the treatment of inherited metabolic disorders, which will be the first clinical evaluation of PROHEMA for the treatment of rare genetic disorders.
- Biological Effects of *Ex Vivo* Programming on Mobilized Peripheral Blood to be Presented at American Society of Hematology (ASH) Annual Meeting. On Saturday, December 6, 2014, the Company plans to present preclinical data at ASH demonstrating the therapeutic potential of *ex vivo* programming on mobilized peripheral blood, which is currently the predominant cell source used in hematopoietic stem cell (HSC) transplantation. The Company will present genome-wide expression analyses characterizing the effects of *ex vivo* programming on CD34+ cells as well as on the T cell compartment, including CD8+, CD4+, Natural killer cells and Regulatory T cells, using FT1050 (16,16-dimethyl Prostaglandin E2), the pharmacologic modulator of PROHEMA. Data from various *in vitro* and *in vivo* model systems, including colony forming assays, cell viability, transwell migration, mixed lymphocyte reactions and HSC engraftment, will be included in the ASH poster presentation.
- Muscle Satellite Stem Cell Development Efforts to Focus on iMPC Program. During the second quarter of 2014, the Company initiated a new program focused on the development of an induced pluripotent stem cell (iPSC)-derived myogenic progenitor cell therapeutic (iMPC) for muscle regeneration. With the Company's increased focus and resource allocation towards advancing and expanding its pipeline of cellular therapeutics, including iPSC-derived cellular therapeutics, the Company has elected not to advance a lead Wnt7a-based protein analog towards clinical development at this time. The Company will continue to assess the biology of Wnt7a-based proteins as part of its broader ongoing research in muscle regeneration.

#### Financial Results & Financial Guidance

• Cash Position: Cash and cash equivalents as of September 30, 2014 were \$45.5 million, compared to \$54.0 million as of December 31, 2013. The decrease is primarily driven by the Company's use of cash in operating activities of \$16.3 million during 2014, which was offset by proceeds from the Company's debt financing activities with Silicon Valley Bank (SVB) during the third quarter of 2014. SVB agreed to make loans to the Company in an aggregate principal amount of up to \$20 million, of which \$10 million was immediately available and \$10 million remains available subject to the achievement of a specified clinical milestone relating to the Company's Phase 2 clinical trial of PROHEMA. The Company accessed \$10 million of the debt facility during the third quarter of 2014.

- **Total Operating Expenses:** Total operating expenses for the third quarter of 2014 were \$6.0 million, compared to \$5.4 million for the third quarter of 2013. Operating expenses for the third quarter of 2014 include \$0.5 million of stock compensation expense, compared to \$1.0 million for the third quarter of 2013.
- **R&D Expenses:** Research and development expenses for the third quarter of 2014 were \$4.1 million, compared to \$3.4 million for the third quarter of 2013. The increase in R&D expenses is primarily related to additional headcount and costs associated with the Company's conduct of its PUMA study and preparation for the commencement of its PROMPT and PROVIDE studies. Research and development expenses for the third quarter of 2014 include a stock-based compensation charge of \$0.3 million.
- **G&A Expenses:** General and administrative expenses for the third quarter of 2014 were \$1.9 million, compared to \$2.0 million for the third quarter of 2013. The decrease in G&A expenses is primarily related to a decrease of \$0.4 million in non-employee stock-based compensation expense, which was partially offset by an increase in compensation and benefits expense, including from the hiring of additional headcount to support the expansion of the Company's financial and administrative operations. General and administrative expenses for the third quarter of 2014 include a stock-based compensation charge of \$0.2 million.
- **Common Shares Outstanding:** Common shares outstanding as of September 30, 2014 were 20.6 million, compared to 20.4 million as of December 31, 2013. Common shares outstanding as of both dates reflect the impact of the Company's IPO on October 4, 2013 which included the automatic conversion of the Company's convertible preferred stock into common stock, the automatic conversion of the Company's convertible promissory notes into common stock and the issuance of common stock upon the retirement of the Company's exchangeable share liability.
- **Financial Guidance.** Fate expects that its existing cash, cash equivalents and marketable securities will be sufficient to fund its operations into early 2016.

#### **Today's Conference Call and Webcast**

The Company will conduct a conference call on Tuesday, November 11<sup>th</sup>, 2014 at 5:00 p.m. EST to report on the Company's financial and operating results for the third quarter ended September 30<sup>th</sup>, 2014 and to provide a corporate update. In order to participate in the conference call, please dial 1-877-303-6235 (domestic) or 1-631-291-4837 (international) and refer to conference ID 30822569. The live webcast can be accessed under "Events & Presentations" in the Investors and Media section of the Company's website at www.fatetherapeutics.com. The archived webcast will be available on the Company's website beginning approximately two hours after the event.

#### About Fate Therapeutics, Inc.

Fate Therapeutics is a clinical-stage biopharmaceutical company engaged in the discovery and development of pharmacologic modulators of adult stem cells to treat severe, life-threatening diseases. The Company's approach utilizes established pharmacologic modalities, such as small molecules, and targets well-characterized biological mechanisms to program the fate and enhance the therapeutic potential of adult stem cells. The Company's lead product candidate, PROHEMA®, is an *ex vivo* programmed hematopoietic stem cell, or HSC, therapeutic, which is currently in clinical development for patients undergoing HSC transplantation. The Company is also applying its reprogramming modulators to develop human induced pluripotent stem cell-derived cellular therapeutics, and evaluating the *in vivo* programming of muscle satellite stem cells using its Wnt7a-based protein analogs for muscle regeneration. Fate Therapeutics is headquartered in San Diego, CA. For more information, please visit www.fatetherapeutics.com.

#### **Forward-Looking Statements**

This release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including statements regarding the therapeutic potential of PROHEMA®, the Company's plans with respect to PROHEMA and other product candidates, anticipated clinical and development milestones (including the timing and results of ongoing and planned clinical trials, the availability of clinical data and results, and the plans of the Company to undertake certain research and development activities including the evaluation of iPSC-derived cellular therapeutics and its continuation of research activities related to Wnt7a protein analogs), the availability of additional funding under the Company's debt facility with SVB, and the sufficiency of the Company's capital position over future periods. These and any other forward-looking statements in this release are based on management's current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. These risks and uncertainties include, but are not limited to, the risks that the results of PROHEMA observed in prior preclinical and clinical development may not be replicated or may cause unanticipated adverse effects in current or subsequent clinical trials of PROHEMA, the risk of cessation or delay of any clinical development activities for a variety of reasons (including additional information that may be requested or additional obligations that may be imposed by the FDA, any difficulties or delays in patient enrollment in current and planned clinical trials, and any adverse events or other negative results that may be observed in these trials), or the risk that we are unable to conduct or complete preclinical activities necessary to identify or advance any iPSC-derived cellular therapeutic product candidates or to advance our Wnt7a protein analogs. For a discussion of other risks and uncertainties, and other important factors, any of which could cause our actual results to differ from those contained in the forward-looking statements, see the risks and uncertainties detailed in the Company's periodic filings with the Securities and Exchange Commission, including but not limited to the Company's Form 10-Q for the quarter ended June 30th, 2014, and from time to time the Company's other investor communications. Fate Therapeutics is providing the information in this release as of this date and does not undertake any obligation to update any forwardlooking statements contained in this release as a result of new information, future events or otherwise.

## Availability of Other Information about Fate Therapeutics, Inc.

Investors and others should note that we routinely communicate with our investors and the public using our company website (www.fatetherapeutics.com) and our investor relations website (ir.fatetherapeutics.com), including without limitation, through the posting of investor presentations, Securities and Exchange Commission filings, press releases, public conference calls and webcasts on our websites. The information that we post on these websites could be deemed to be material information. As a result, we encourage investors, the media, and others interested in Fate Therapeutics to review the information that we post on these websites on a regular basis. The contents of our website, or any other website that may be accessed from our website, shall not be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended.

# Condensed Consolidated Statements of Operations and Comprehensive Loss (in thousands, except share and per share data)

	Three Months Ended September 30,					Nine Months Ended September 30,			
		2014		2013		2014		2013	
D				(unauc	lited)				
Revenues:	Φ		¢	200	¢		¢	(2)	
Collaboration revenue	\$	_	\$	209	\$	_	\$	626	
Grant revenue								345	
Total revenue		_		209		_		971	
Operating expenses:									
Research and development		4,080		3,378		12,570		8,976	
General and administrative		1,904		1,979		6,391		4,768	
Total operating expenses		5,984		5,357		18,961		13,744	
Loss from operations		(5,984)		(5,148)		(18,961)		(12,773)	
Other income (expense):									
Interest income		—		2		1		3	
Interest expense		(187)		(230)		(258)		(418)	
Loss on extinguishment of debt		(432)				(432)		—	
Change in fair value of exchangeable shares				(728)				(1,988)	
Change in fair value of warrant liability				31				21	
Total other expense, net		(619)		(925)		(689)		(2,382)	
Net loss and comprehensive loss	\$	(6,603)	\$	(6,073)	\$	(19,650)	\$	(15,155)	
				<u>.                                    </u>		<u> </u>		<u> </u>	
Net loss per common share, basic and diluted	\$	(0.32)	\$	(4.81)	\$	(0.96)	\$	(12.24)	
Weighted-average common shares used to compute basic and									
diluted net loss per share		20,489,181		1,262,546		20,435,073		1,238,567	

# Condensed Consolidated Balance Sheets (in thousands)

	 September 30, 2014 (unaudited)		December 31, 2013	
Assets				
Current assets:				
Cash and cash equivalents	\$ 45,530	\$	54,036	
Prepaid expenses and other assets	94		615	
Total current assets	 45,624		54,651	
Long-term assets	1,386		932	
Total assets	\$ 47,010	\$	55,583	
Liabilities and Stockholders' Equity				
Current liabilities:				
Accounts payable and accrued expenses	\$ 3,167	\$	2,721	
Other current liabilities	745		1,879	
Total current liabilities	3,912		4,600	
Long-term debt, less current portion	9,389		_	
Other long-term liabilities	133		135	
Stockholders' equity	33,576		50,848	
Total liabilities and stockholders' equity	\$ 47,010	\$	55,583	

# Contact:

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